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Supreme Court of the United States

OCTOBER TERM, 1959

DYESPECIES & CHEMICALS, INC., *Petitioner*,

v.

ARTHUR S. FLEMMING, Secretary of Health, Education and Welfare, *Respondent*.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

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Petitioner prays that a writ of certiorari issue to review the judgment of the Court of Appeals for the Eighth Circuit rendered on October 30, 1959, (Appendix p. 14a). This judgment affirmed the order promulgated by respondent on February 6, 1959, (R. 1).

OPINIONS BELOW

The opinion of the Court of Appeals, which is reported at 271 F.2d 281, is printed as an Appendix to this petition.

The order of respondent is reported at 24 Fed. Reg. 883 and appears in the record at page 47.

JURISDICTION

The judgment of the Court of Appeals for the Eighth Circuit was entered on October 30, 1959. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTION PRESENTED

The Congress has provided in 21 U.S.C. §§ 371(e)(2) and (3) that prior to amendment of the food color certification regulations, persons adversely affected "may file objections thereto with the Secretary" and request a public hearing upon such objections after which the Secretary

> "shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections."

The following question is presented:

May the Secretary amend the food color certification regulations without holding a public hearing because prior objections, which were filed with respect to a prior proposed amendment, raised issues that are no longer deemed relevant, or must persons adversely affected be given the opportunity to file objections and have a public hearing based on issues of fact and law which are relevant to the amendment as announced?

STATUTES INVOLVED

Section 406(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 346(b)) provides that

> "The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents."

Sections 701(e)(2) and (3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 371(e)(2) and (3)) provide that

> "(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor and requesting a public hearing upon such objections.
>
> (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions."

STATEMENT

Petitioner is and for forty years has been a producer of food colors, two of which, known as FD&C Yellows 3 and 4, are used to color edible fat products such as

butter and oleomargarine. Until the administrative action that forms the basis for this petition, these two colors had been certified as safe for use as food colors by respondent pursuant to the provisions of the Federal Food, Drug and Cosmetic Act (hereafter the Food and Drug Act). On February 6, 1959, respondent, without notice or hearing, promulgated an Order (24 Fed. Reg. 883) which purported to amend the regulations under § 406(b) of the Food and Drug Act so as to exclude the two colors in question and thus prevent their certification for use as food colors.

Judicial review of this Order was sought by petitioner in the court below pursuant to the provisions of § 701(f) of the Food and Drug Act. In its petition for judicial review, petitioner questioned the validity of respondent's action on the ground that it had been taken without affording petitioner the right to file relevant objections thereto and without a public hearing both of which are required by the provisions of the Food and Drug Act. Petitioner requested the court below to direct respondent to consider the objections that petitioner and others adversely affected were entitled and prepared to make so that there might be a record of relevant evidence on which respondent's action might be properly reviewed. The court below sustained respondent's Order and denied the requested relief on the ground that petitioner's prior objections, which were filed to an earlier Order proposed in 1957, were no longer relevant because they did not meet the subsequent test laid down by this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, which formed the basis of respondent's Order of February 6, 1959. It thus held that, as the only objections that had been filed were to be regarded

as a nullity, respondent was not required to hold a public hearing to consider them.

The context of this curious holding below is as follows:

On January 24, 1957, respondent first proposed the exclusion of the two colors here in question from the list of certified colors and invited interested persons to submit comments within thirty days (22 Fed. Reg. 478) (R. 1).

On May 4, 1957, respondent published the text of an order providing for the delisting of the two food colors. The order, which by its terms was to become effective ninety days thereafter, stated that objections and requests for a public hearing should be submitted by persons adversely affected within thirty days (22 Fed. Reg. 3173) (R. 40). Petitioner, among others, filed timely objections to the order which were predicated upon what was then thought to be the correct construction of the statutory test contained in § 406(b) of the Food and Drug Act. That is, the factual issues raised by petitioner's objections as filed concerned the question of whether the food colors in question were harmless if used as intended. On August 17, 1957, the proceeding was stayed in its entirety by the promulgation of an order which in pertinent part stated:

> "Within the time allowed, objections were received [to the order of May 4, 1957] from firms asserting that the order if placed into effect would adversely affect them, specifying objections, stating grounds therefor, and requesting a public hearing. The objections filed protested each of the provisions of the above-referenced amending order.

> Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 701(e); 52 Stat. 1055; 70 Stat. 919; 21 U.S.C. 371(e)) and to the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education and Welfare (22 F.R. 1045): *It is ordered*, That the amendments to the regulations for color certification made in the order published in the Federal Register of May 4, 1957 (22 F.R. 3173), are stayed in their entirety.
>
> In accordance with the provisions of section 701 of the Federal Food, Drug, and Cosmetic Act, the Commissioner of Food and Drugs will subsequently announce a hearing for the purpose of receiving evidence relevant and material to the issues raised by the objections filed to the order." (22 Fed. Reg. 6613) (R. 46).

No hearing was announced, however, and the proceeding was continued in a pending status. Then, on December 15, 1958, this Court handed down its opinion in *Flemming* v. *Florida Citrus Exchange*, *supra*. There it was determined that the relevant factual question was whether a food color was capable of causing harm in laboratory animals when fed at "toxicologically significant" levels, even though these levels were many times those present under conditions of actual use in food. Hence, the only factual issue which petitioner had considered or contested in its 1957 objections became irrelevant. Without affording petitioner an opportunity to submit objections and evidence, based on the new criterion, respondent promulgated the Order here in question, on February 6, 1959 (24 Fed. Reg. 883) (R. 1). That Order noted that although a public hearing had been requested when the earlier Order had been proposed, "no purpose could be served by holding

a public hearing" because the earlier objections had sought to raise the wrong factual issue and thus were now "without substance."

REASONS FOR GRANTING THE WRIT

The Court of Appeals, on the basis of what all concede to be an irrelevant record, albeit the only possible record in the circumstances, has erroneously decided an important question of Federal law in a way which conflicts with a decision of this Court.

The court below rested its decision on the conclusion that petitioner's four stated "grounds for objections" to the Order of May 4, 1957, "were insufficient to warrant a hearing" on the Order of February 6, 1959. In other words, the pre *Florida Citrus* objections filed by petitioner were no longer "relevant and material to the issues" which formed the basis of the Order promulgated after that decision. The court below, having so phrased the question could only conclude that no hearing was warranted under *Denver Union Stock Yard Co.* v. *Producers Livestock Marketing Ass'n*, 356 U.S. 282, and *United States* v. *Storer Broadcasting Company*, 351 U.S. 192. The answer one receives depends on the way the question is asked. Thus, if the 1957 objections are viewed as being filed to the 1959 Order, these cases may be said to hold that, despite the statutory requirement that a hearing be held, no hearing is needed to consider complaints or objections which "do not state a valid basis for a hearing." However, neither *Denver Union Stock Yard* nor *Storer* is support for the unthinkable proposition that petitioner's right to be heard on the 1959 Order is to be judged on the basis of the dated learning contained in its May 27, 1957, objections.

Petitioner did not know until December 15, 1958, the day the *Florida Citrus* opinion was handed down, that its prior objections did "not state a valid basis for a hearing." After that date, respondent's actions were so paced that no opportunity was afforded for new and pertinent objections. The new Order was simply promulgated on February 6, 1959, and petitioner was told that its prior objections were insufficient. Indeed, they could not have been otherwise but for a clairvoyant anticipation by petitioner in early 1957 of the opinion in *Florida Citrus*. There is nothing in that opinion which condones such a result. In fact, the opinion assumes that the new test will be applied in regulations subject to the notice and hearing requirements of the Act.

In *Florida Citrus*, the Court held that the relative factual test for certification, whether a color, as used, "was harmful for human consumption," had been properly supplanted by the factual requirement that the colors in question be "wholly innocuous and demonstrated to be without adverse physiological effect."

> "This rule of caution is here one which relieves the Secretary from the burden of showing in each case that a food containing them raises a possibility of injury to health, and requires that the color stuffs, whose positive values are only visual and which are not naturally found in foods, not be added unless they could pass a higher standard." 358 U.S. at 162.

This Court's approval of the new rule settled the question of the showing required of the Secretary at the public hearing provided by the statute. It did not, as the court below assumed, vest in respondent that uncontrolled discretion to decertify a color with-

out a hearing which he exercised by his Order of February 6, 1959. The opinion of this Court in *Florida Citrus*, though it approves as the test for certifiability of coal-tar colors the harmlessness of the color itself, recognizes expressly that the Secretary's determination must be based on appropriate laboratory tests adduced at the public hearing required by the statute. Before delisting any coal-tar color, the Secretary must establish that the color is not "harmless" when administered "at toxicologically significant levels." 358 U.S. at 163. What petitioner sought below and what it asks here is no more than its statutory right to test, under the provisions of the Act at the public hearing contemplated by the Act, the toxicological data on which respondent purports to have relied in promulgating his Order of February 6, 1959.

Because of respondent's refusal to hold a public hearing, there is, of course, no "substantial evidence of record" to support the Order here in question. The Court below condoned respondent's arbitrary assumption that, because he had unilaterally concluded that the two food colors in question are "not harmless", public hearings could serve no purpose. This bald misapplication of *Florida Citrus* is strikingly revealed by a subsequent order of respondent, dated January 8, 1960, purporting to withdraw the certification of previously certificated batches of coal-tar colors, including FD&C Yellows No. 3 and 4. In the Order issued earlier this month, respondent recites:

> "Dyestuffs and Chemicals, Inc., filed objections requesting a hearing on the completeness, adequacy, and accuracy of the factual basis for the Department's action in removing FDC Yellows No. 3 and 4 from the approved list. Since the

> order decertifying these colors has been reviewed by the Court of Appeals for the Eighth Circuit and the Department's order has been affirmed, such regulations may not be challenged anew in this proceeding. Such objections are without legal validity and do not call for a public hearing." (25 Fed. Reg. 142).

Hence the decision of this Court in *Florida Citrus* —establishing the standard for certifiability of coal-tar colors as harmlessness when "administered at toxicologically significant levels"—has been distorted by the court below to foreclose petitioner's statutory right to test at a public hearing the evidentiary basis for respondent's conclusions. But the newly approved standard, or any other standard, is wholly meaningless until and unless it is put into the proper factual context by means of administrative proceedings. Without such proceedings the standard will mean only what respondent says it means. All objections may be disregarded as immaterial. And, of course, there will be nothing to review judicially. Such a result both vitiates the statutory command and, in fact, squarely conflicts with the *Florida Citrus* decision of this Court.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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